## 10. Premarket Notification 510(k) Safety and Effectiveness Summary

## HERMESTM Control Center 510(k) Summary

Computer Motion, Inc. is submitting the following safety and effectiveness summary.

1) Submitter Information:

Computer Motion 130-B Cremona Drive Goleta, CA 93117

Contact: David U. Thomas, Regulatory Affairs Specialist

Phone: (805) 968-9600 Ext. 214

FAX (805) 685-9277 Prepared: October 12, 2000

2) Name of Device:

Proprietary Name: HERMES<sup>TM</sup> Port Expander

Common Name is Port Expander

Classification Name: Laparoscope for Use in General and Plastic Surgery, Regulation

Number 876.1500, Class II.

- 3) Substantially equivalent to HERMESTM Control Center (510(k)'s K973700 and K991444).
- 4) The Port Expander is a low profile expansion unit with a single HERMES Interface cable (USB-type) connection to the HERMES System and eight additional HERMES Interface connections to Remote Devices.

The intent of the HERMES Port Expander is to allow an increase in the number of devices that can be connected to the HERMES control center through increasing the number of ports available to connect devices from eight to fifteen. The devices to be controlled will not change from the devices that can currently be controlled by the HERMES Control Center.

The HERMES OR Control Center and Port Expander are indicated for use with the Stryker Endoscopy 882 Camera, Quantum 5000 Light Source, Stryker SE5 Shaver, W.O.M. 20L Insufflator and W.O.M. 2.0L Arthroscopy Pump, the Stryker Total Performance System, Berchtold Surgical Lights, AESOP HR and Steris Amsco Table Model SP3085. It can be used in general laparoscopy, nasopharyngoscopy, ear endoscopy, and sinuscopy where a laparoscope/endoscope is indicated for use. A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & thorascopic anterior spinal fusion, decompression fixation, wedge resection, lung biopsy, pleural biopsy,

dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization in indicated and examination of the evacuated cardiac chamber during performance of valve replacement. The users of the HERMES ORCC are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists

The HERMES Port Expander was designed and tested to the following standards:

IEC 601-1 Second Edition 1990 International Standard for Medical Electrical Equipment IEC 601-1 Amendment 1 1991 International Standard for Medical Electrical Equipment IEC 601-2-18 First Edition 1990 International Standard for Medical Electrical Equipment UL 2601-1.

Conducted & Radiated Emission EN55022/A1: 1995.

Immunity Tests EN61000-4-2: 1995; EN61000-4-3: 1995; EN50140:1994; EN61000-4-4:1995; EN61000-4-5:1995; EN61000-4-6:1995.

CAN/CSA-C22.2 NO. 601.1-M90 & NO. 601.2.18-92.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

NOV - 3 2000

Mr. David U. Thomas Regulatory Affairs Specialist Computer Motion, Inc. 130 Cremona Drive, Suite B Goleta, California 93117

Re: K003217

Trade Name: Hermes Port Expander

Regulatory Class: II Product Code: GCJ

Dated: October 12, 2000 Received: October 13, 2000

Dear Mr. Thomas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and

Radiological Health

Enclosure

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510(k) Number (if known): K00 3217	-			
Device Name: HERMES™ Port Expander				
Indications For Use:				

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NEEDED)	
Concurrence of CDRH, Office of Device Evaluation (ODE)	
that Phodu	***
(Division Sign-Off)	
Division of General Restorative Devices	
510(k) Number K 003217	

OR

Prescription Use X (Per 21 CFR 801.109) Over-The-Counter Use\_